FEB 2 5 2014

510(k) Summary

JJGC Indústria e Comércio de Materiais Dentários SA

Neodent Implant System

December 2, 2013

Manufacturer Name	JJGC Indústria e Comércio de Materiais Dentários SA Av. Juscelino Kubitschek de Oliveira, 3291 - CIC Curitiba, Paraná, 81270-200, Brazil Telephone: +55 41 2169 1003 Fax: +55 41 2169 1043
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Neodent Implant System
Common Name	Endosseous dental implant abutment
Classification Regulations	Class II, 21 CFR 872.3630
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

DEVICE DESCRIPTION

The purpose of this submission is to expand the Neodent Implant System components cleared under K101945 and K123022. This submission includes Facility Universal Post and Equator Attachment CM abutments with a Morse taper interface. Facility Universal Post abutments are straight, post-type abutments for cemented prosthetic restorations. They are provided in one platform diameter (3.3 mm), gingival heights of 1 mm to 5 mm, and prosthetic heights of 4 mm and 6 mm. Facility Universal Post abutments are compatible with the Facility dental implants cleared in K123022, and with the Universal Post Cylinders cleared in K101945. Equator Attachment CM abutments are straight, ball-type abutments for the attachment of overdentures or partial dentures. They are provided in five gingival heights (1.5, 2.5, 3.5, 4.5 and 5.5 mm). These abutments have a titanium nitride (TiN) coating for the purpose of creating a harder surface to increase wear resistance. This titanium nitride coating is identical to that used on the Neodent CM Mini Ball Attachment cleared in K101945, and the Facility Equator Attachment cleared in K123022. Equator Attachment CM abutments are compatible with Titamax CM, Titamax CM EX, and Alvim CM implants cleared in K101945, and with the CM Drive implants cleared in K123022. All abutments in this submission are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).*

EQUIVALENCE TO MARKETED DEVICE

Neodent Implant System is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K101945

JJGC Indústria e Comércio de Materiais Dentários SA, Neodent Implant System, K123022

The subject device and the predicate devices have the same intended use, have similar technological characteristics, have similar designs and dimensions, use the same materials and the same surface treatment (titanium nitride) as abutments cleared under K101945 and K123022. The subject device and predicate devices encompass the same range of physical dimensions, including prosthetic height, gingival height, platform diameter, and angulation (straight). The subject and predicate devices are packaged in the same materials and sterilized using the same methods.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility, engineering analysis and dimensional analysis. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Clinical data were not submitted in this premarket notification.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

JJGC Indústria e Comércio de Materiais Dentários SA
C/O Dr. Kevin Thomas
Regulatory Consultant
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K133696
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 3, 2014
Received: February 4, 2014

Dear Dr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
-S FDA

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K133696

Device Name: Neodent Implant System

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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